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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,457	02/21/2002	Anne M. Pianca	98P1021US08	3029

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EXAMINER
EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,457	Applicant(s) PIANCA ET AL.	
	Examiner George R Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/28/03 has been entered.

Response to Amendment

The declaration filed on 2/28/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the Chastain et al reference for the following reasons.

All the inventors of the subject matter claimed have not submitted declarations. (See MPEP 715.04)

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Chastain reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). Exhibit A does not show or describe the at least one electrode oriented towards the vessel wall. (Although, it could be argued that this would have been obvious to one having ordinary skill in the art at the time the invention was made.)

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Chastain reference. The declaration states that the inventors continued "to work to reduce the inventions to practice" as evidenced by exhibit C. Exhibit C shows no work of reduction to practice and only that the attorney, Mr. Schoenbaum, received information that was requested. What information was needed or provided has not been given. That information could have been a list of inventors, title change, etc. and that information has not been shown to be work of reduction to practice. A reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Chastain reference to either a constructive reduction to practice or an actual reduction to practice. Exhibit B does not contain a date (See MPEP 715.07) to show diligence. Since no reduction to practice has been shown, the Examiner has concluded that the 1.131. declaration is used to show "conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to the filing date of the application" to show facts sufficient to establish prior invention of the claimed subject matter (See MPEP 715.07). Therefore, all exhibits after conception must contain a date since they are relied upon for diligence.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 6, 9, 11, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain et al, 5925073, in view of Swoyer, 5683445. Since a guidewire is used in Chastain through the lumen, it is inherent that there be a distal opening in the lead (in the alternative, see the 103 rejection below).

Chastain discloses the claimed invention and providing an anchor in the coronary sinus to stabilize the electrode, but does not teach having a tip electrode and canted portion that orients the tip electrode toward the vessel wall. Swoyer teaches that it is known to have a coronary sinus anchor lead have a tip electrode and canted portion that orients the tip electrode toward the vessel wall to provide effective stimulation of the heart. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coronary sinus anchor lead as taught by Chastain, with a tip electrode and canted portion that orients the tip electrode toward the vessel wall as taught by Swoyer, since such a modification would provide a

coronary sinus anchor lead with a tip electrode and canted portion that orients the tip electrode toward the vessel wall to provide effective stimulation of the heart.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain et al in view of Swoyer.

Chastain in view of Swoyer discloses the claimed invention except for the ring electrode located on, before, or after the bends. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the anchoring lead as taught by Chastain in view of Swoyer, with the use of a ring electrode on, before or after the bends since it was known in the art that ring electrodes are included anywhere on leads to provide bipolar sensing and pacing or additional sensing and pacing.

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain et al in view of Swoyer as applied to claims 6 and 1 above.

Chastain in view of Swoyer discloses the claimed invention except for the humps being in different geometric planes. It would have been an obvious matter of design choice to one skilled in the art to modify the anchoring lead as taught by Chastain in view of Swoyer with the humps in the anchor being located in different geometric planes, since applicant has not disclosed that providing the humps in different geometric planes provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any location of the humps, such as the humps being located in the same plane as taught by Chastain in view of Swoyer to anchor the lead in the coronary sinus.

Claims 3, 7, 8, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain in view of Swoyer as applied to claims 2, 6, and 1 above.

Chastain in view of Swoyer discloses the claimed invention except for the lead having a distal opening to receive a guidewire, the stylet having a tapered portion, the first and second bend located in the range of 0.15-0.7 inches from the distal end and first bend, and the lead having a textured region of ePTFE or porous material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical electrical lead as taught by Chastain in view of Swoyer with the lead having a distal opening to receive a guidewire, the stylet having a tapered portion, and the lead having a textured region of ePTFE or porous material (such as silicone rubber, polyurethane, or ceramic) since it was known in the art that medical electrical leads have a distal opening to receive a guidewire to allow the lead to be positioned in the body, that leads use a stylet with a tapered portion to allow the stylet to fit in the narrow distal end of the lead and to position the lead, and that leads have a textured region of ePTFE or porous material to allow the lead to anchor in the body.

In addition, it would have been an obvious matter of design choice to one skilled in the art to modify the medical electrical lead as taught by Chastain in view of Swoyer to include ePTFE as the textured region and the first and second bends being located 0.15-0.7 inches from the distal end and first bend, since applicant has not disclosed that ePTFE and the first and second bends being located 0.15-0.7 inches from the distal end and first bend provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any biocompatible textured material or any location of the bends, such as silicone rubber, polyurethane or ceramic for allowing the lead to anchor in the body as taught by Chastain in

view of Swoyer and in view of one having ordinary skill in the art for allowing the lead to anchor in the coronary sinus or such as the S-shaped or zig-zag shaped lead location of the bends as taught by Chastain in view of Swoyer to allow the lead to anchor in the coronary sinus.

Claims 1, 2, and 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swoyer in view of Chastain et al (5925073).

Swoyer discloses the claimed invention to anchor a lead in the coronary sinus except for the lead having an s-shape with a plurality of bends for the anchoring. Chastain teaches that it is known to use an s-shaped lead with a plurality of bends to anchor a lead in the coronary sinus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Swoyer, with the s-shaped lead with a plurality of bends as taught by Chastain, since such a modification would provide a lead with an s-shape with a plurality of bends to anchor a lead in the coronary sinus.

In the alternative, it would have been an obvious matter of design choice to one skilled in the art to modify the anchoring lead as taught by Swoyer with the use of an s-shape anchor with a plurality of bends, since applicant has not disclosed that the s-shape with a plurality of bends provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any shape that was non-helical, such as the J-shape or C-shape as taught by Swoyer for anchoring the lead in the coronary sinus.

Claims 1, 2, 4, 5, 6, 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness et al. Alferness states in column 7, line 60, that his fixation section may also be a "serpentine" configuration (a sinuous or sine curve configuration) and will therefore meet the limitation of at least two non-helical s-shaped bends

Alferness discloses the claimed invention except for the lead being shaped to allow the electrode to contact cardiac tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Alferness, with the lead being shaped to allow the electrode to contact cardiac tissue since it was known in the art that heart leads include the lead being shaped to allow the electrode to contact cardiac tissue to effectively stimulate the cardiac tissue and allow selection of a particular area to be stimulated.

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness et al claims 6 and 1 above.

Alferness discloses the claimed invention except for the humps being in different geometric planes. It would have been an obvious matter of design choice to one skilled in the art to modify the anchoring lead as taught by Alferness with the humps in the anchor being located in different geometric planes, since applicant has not disclosed that providing the humps in different geometric planes provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any location of the humps, such as the humps being located in the same plane as taught by Alferness to anchor the lead in the coronary sinus.

Claims 3, 7, 8, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness as applied to claims 2, 6, and 1 above. Alferness discloses the use of a guidewire with

the lead and therefore the lead will inherently have a distal opening. In the alternative, see the 103 rejection below.

Alferness discloses the claimed invention except for the lead having a distal opening to receive a guidewire, the stylet having a tapered portion, the first and second bend located in the range of 0.15-0.7 inches from the distal end and first bend, and the lead having a textured region of ePTFE or porous material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical electrical lead as taught by Alferness with the lead having a distal opening to receive a guidewire, the stylet having a tapered portion, and the lead having a textured region of ePTFE or porous material (such as silicone rubber, polyurethane, or ceramic) since it was known in the art that medical electrical leads have a distal opening to receive a guidewire to allow the lead to be positioned in the body, that leads use a stylet with a tapered portion to allow the stylet to fit in the narrow distal end of the lead and to position the lead, and that leads have a textured region of ePTFE or porous material to allow the lead to anchor in the body.

In addition, it would have been an obvious matter of design choice to one skilled in the art to modify the medical electrical lead as taught by Alferness to include ePTFE as the textured region and the first and second bends being located 0.15-0.7 inches from the distal end and first bend, since applicant has not disclosed that ePTFE and the first and second bends being located 0.15-0.7 inches from the distal end and first bend provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any biocompatible textured material or any location of the bends, such as silicone rubber, polyurethane or ceramic for allowing the lead to anchor in the body as taught by Alferness and in view of one having

ordinary skill in the art for allowing the lead to anchor in the coronary sinus or such as the serpentine S-shaped lead location of the bends as taught by Alferness to allow the lead to anchor in the coronary sinus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

George R Evanisko
Primary Examiner
Art Unit 3762

3/24/3

GRE
March 24, 2003